DEPARTMENT OF HEALTH AND HUMAN SERVICES

94930d

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

August 18, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2004-15

Robert A. Collins, President
Impro Products Inc.
3 Allamakee Street
P.O. Box 147
Waukon, IA 52172

Dear Mr. Collins:

Recently inspections were made of your veterinary drug manufacturing operation located at 3 Allamakee Street, Waukon, Iowa. The inspections were conducted on August 26-27, 2003, and March 23, 2004, by a Food and Drug Administration (FDA) Investigator. It revealed that your firm is marketing several Whey Blend products in violation of the federal Food, Drug, and Cosmetic Act (the Act).

The labeling for these products includes 13 microbiologic taxonomy terms (12 microorganisms are listed by [redacted] such as Staphylococcus and Streptococcus and one is listed by [redacted] staining classification), implying that they have an antimicrobial effect. The implied antimicrobial effect is further supported by the labeling statement that the whey is "processed from milk produced by dairy cows exposed to a known environment." The labeling also states that the products are to be administered before calving and as indicated during lactation and that no milk withholding is required. Moreover, the products are packaged in parenteral (or injectable) type bottles with a rubber stopper and metal crimp top.

The labeling and packaging for these products indicate that they are intended for use, among other things, in the cure, prevention, and treatment of disease in animals and/or to affect the structure or function of their bodies, causing the products to be drugs as defined in section 201(g) of the Act. Because we have no evidence that your products are generally recognized as safe and effective by scientific experts, for the labeled intended use, they are regarded as new animal drugs under section 201(v) of the Act. As a new animal drug, this product is unsafe within the meaning of Section 512 of the Act since it is not the subject of a New Animal Drug Application (NADA), and it is therefore adulterated within the meaning of section 501(a)(5) of the Act.

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure adherence to each requirement of the Act and its implementing regulations.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action, such as seizure and/or injunction, without further notice.

Please notify this office in writing within fifteen (15) working days of receiving this letter of the specific steps you have implemented, or are planning to implement, to prevent a recurrence of the violations noted above. Include copies of any available documentation demonstrating that corrections have been made. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to Mr. Joseph G. Kramer, Compliance Officer, at the address noted in the letterhead.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District